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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,613	08/17/2001	James P. Beltzer	DYXHGS-025.1 US	5083

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,613	BELTZER ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-16,31,32 and 70-89* is/are pending in the application.

4a) Of the above claim(s) *14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,15,31,32 and 70-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2005*.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 1-18-05 has been entered into the record. The substitute specificaiton has been entered. Claims 1-11, 17-30 and 33-39 have been cancelled. Claims 12-6, 31-32, 70-89 are pending. Claims 12, 13, 15, 31, 32 and 70-89 are under examination as drawn to the elected species SEQ ID NO:457 (common core sequence of SEQ ID NO:448). The other core sequences as represented by SEQ ID NOS;1-12, 446 and 447 are withdrawn from consideration.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims drawn to us of core sequence comprising SEQ ID NOS 1-12, 446, 447 drawn to an invention nonelected inventions with traverse in the response filed 5-8-03. The restriction requirement based on linking claims analysis is maintained in view of the non-allowance of the linking claim 69. A complete reply to the final rejection must include cancellation of nonelected claims/subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

It is noted claim 70 is rejoined for examination in view of the amendment to the claim to read on the elected species/core sequence.

Information Disclosure Statement

The supplemental information disclosure statement filed 2-05 has been considered and initialed copy is enclosed. Applicants note in the response of 1-18-05 that they have enclosed copies of references that were previously provided. However, the foreign and non-patent literature of the information disclosure statement of 9-3-02 is still not of record.

Objections/Rejections Withdrawn

The rejection of claims 21-24, 29, 31, 67 and 69 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn based on either the cancellation of the claim or the amendment to the claims.

The rejection of claims 1, 2, 3, 5, 12, 13, 15, 17, 18, 19, 21-32, 67 and 68 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants' amendment or cancellation of the claim.

The rejection of claims 1, 2, 3, 12, 13, 17, 18, 19, 21, 25, 29, 30, 31, and 32 under 35 U.S.C. 102(b) as being clearly anticipated by Browning et al (WO 00/43032, published July 27, 2000) is withdrawn in view of Applicants' amendment or cancellation of the claim.

The rejection of claims 21-32 under 35 U.S.C. 102(b) as being clearly anticipated by Yan et al (Nature Immunology, 1(1):37-41, July 2000) is withdrawn in view of Applicants' amendment or cancellation of the claim.

The rejection of claims 21-32 under 35 U.S.C. 102(b) as being clearly anticipated by Xia et al (J.Exp.Med., 1(3):137-143, July 3, 2000) is withdrawn in view of Applicants' amendment or cancellation of the claim.

The rejection of claims 1, 2, 3, 5, 12, 13, 15, 17, 18, 19, 29, 30, 31, and 32 under 35 U.S.C. 102(b) as being clearly anticipated by Gross et al (Nature, 404:995-999, April 27, 2000) is withdrawn in view of Applicants' amendment or cancellation of the claim.

The rejection of claims 1, 2, 3, 12, 13, 17, 18, 19, 29, 30, 31, and 32 under 35 U.S.C. 102(e) as being clearly anticipated by Shu (U.S. Patent No. 6,475,987, issued Nov 5, 2002, filed May 5, 2000 with claimed priority to US provisional applications filed on May 6, 1999 and May 1, 2000) is withdrawn in view of Applicants' amendment or cancellation of the claim.

The rejection of claims 1, 2, 3, 5, 12, 13, 15, 17, 18, 19 and 21-32 under 35 U.S.C. 102(b) as being clearly anticipated by Theill et al (U.S, Patent Application Publication 2002/0081296, published June 27, 2002, filed May 14, 2001 with claimed priority to US provisional applications filed May 12, 2000 and June 27, 2000) is withdrawn in view of Applicants' amendment or cancellation of the claim.

Objections/Rejections Maintained

The objection to the specificaiton is maintained in view of the lack of multiple trademarks in the specification that are not accompanied by the generic terminology. As previously stated Applicants should check the specification for specific trademarks and amend the specification accordingly. As such, this term must also comply with the use of trademarks in the application and in the claims. Correction is still required.

Claims 12, 13, 15, 31-32, 70, 71 and new claims 72-89 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a either a *specific and*

substantial asserted utility or a well established utility is maintained for reasons made of record in the Office Action mailed 7-14-04.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the treatment of disease is a well-established utility. This is not persuasive, there is no generic treatment for prevention or treatment of all immune disorders. Further, there is no peptide treatment known to the art that provides for treatment of all the plethora of diseases or disorders contemplated by the specification. Applicants argue that according to the utility guidelines, that since most diseases can be treated that utility rejections should rarely be made. This is not persuasive, a utility rejection is based on the claimed invention. Peptide based therapeutics have no well-established utility in either the treatment of lupus or an treatment of immune diseases/disorders in general. Applicants have not submitted any evidence that establishes for the record that peptide based therapeutics are well-established treatment modalities for immune diseases, autoimmune diseases and lupus in particular. Merely, because a rejection can "rarely" be made is not basis for withdrawing a prima facie case. Applicants argue that the examiner alleges defects in the specific and substantial prongs but not in the credible. This misrepresents the examiners statement. The examiner stated that since the claimed invention did not meet either the substantial or specific prong of the test, credibility was not assessed (see page 11, last line of the rejection). Applicants argue that the claims meet the "specific utility" test because they are drawn to treatment of an immune system disorder or disease. This is not persuasive, system disorder or disease comprises a broad panoply of disorders listed at pages 88-93 of the specification. This laundry list of disorders have disparate origins and/or unknown etiology and also includes treatment/prevention of cancers of the immune system, treatment of blood clotting disorders of the immune system all of which lack a common core mechanism. Applicants argue that no facet of "specific utility" that requires a relationship between a therapeutic agent, its target and a disease or some standard of evidentiary support and quotes MPEP

2107.01. In contrast to applicants' position, this passage supports the examiner in that applicants have not reasonably correlated a B-lymphocyte stimulator protein (BLSP) binding polypeptide with a immune disease or conditions therapeutic. Applicants' exhaustive laundry list of immune disorders, provides for a general statement of therapeutic utility for any immune system diseases and disorders. Neither applicants' specification nor the art recognizes a specific biological activity that reasonably correlates that activity to a disease or condition. There is no correlation between disparate immune disorders or disease such a graft-versus-host disease, cancer and lupus and Applicants have provided none. The specificaiton as filed does provide evidence that the laundry list of immune diseases or disorders have a common core physiology and it would not be readily apparent to one skilled in the art that immune system cancers and lupus have a common core etiology such that the disclosed claimed activity of BLSP-binding reasonably correlates with therapeutic or preventive activity. As such, the use of the peptides is not specific to any particular immune disease or disorder and one skilled in this art and represents a fishing expedition by Applicants. Applicants' specification is entirely prophetic in nature and replete with "may be tested" and "can be tested for use in". The recitation of all of the known immune diseases or disorders is at best a wish list for which the skilled artisan must determine if any immune system disease or disorder can be treated or prevented because there is not a single in vitro or in vivo experiment that establishes that the binding peptides have any activity affecting any immune system parameter either in vitro or in vivo. Applicants argue that therapeutic methods possess "substantial utility" by definition and therefore have a real world context of use and the instant use is not a throw-away use. This is not persuasive, a utility that requires or constitute carrying out of further research to identify or reasonably confirm a real world context of use is not a substantial utility. As previously set forth, supra Applicants specification is entirely prophetic in nature and replete with "may be tested" and "can be tested for use in". Not a single disclosed claimed peptide has been demonstrated to be

effective to treat, prevent any immune disease or disorder or lupus in particular. The only evidence in the specification is that these peptides bind BLSP. There is no disclosed correlation between the binding peptide and any *in vitro* activity that is reasonably correlative of effective treatment or prevention of diseases *in vivo* as claimed. The courts have held that the disclosure is insufficient when testing is necessary to determine the actual use or possible lack of use *(In re Kirk and Petrow* (CCPA 1967) 153 USPQ 48). This specification is devoid of any in vitro finding that the binding peptides have therapeutic function; are able to inhibit or reduce B-cell activation BLSP mediated or otherwise; or interfere with the interaction between BLSP and a BLSP receptor. Not a single peptide was demonstrated in vitro to have any of these activities. There is no in vitro data that would reasonably correlate with treatment of lupus specifically or immune system disorders in general. The examiner emphasizes that NOT a SINGLE peptide claimed as a therapeutic has been demonstrated to have either inhibit or reduce B-cell activation BLSP mediated or otherwise; or interfere with the interaction between BLSP and a BLSP receptor either in vitro or in vivo at the time of filing. The specification is merely an invitation to further experimentation for the skilled artisan to discover which, if any, of the claimed peptides are effective to treat, prevent or ameliorate any immune system disease or disorder. The need for such further research to determine if any of the peptides are effective as claimed clearly indicates that the claimed invention lacks substantial utility as set forth in the utility guidelines. The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1996), in which the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that: "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific

benefit exist in currently available form-there is insufficient justification for permitting an application to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion." The invention is not disclosed in a specific benefit exists in a currently available form and as such lacks "real world" utility because further experimentation is required to ascertain if the BLSP-binding peptides are in fact useful as claimed.

The rejection is maintained.

Claims 12, 13, 15, 31-32, 70, 71 and new claims 72-89 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is maintained for reasons made of record in the Office Action mailed 7-14-04.

Applicant's arguments with respect to the rejection based on a lack of utility have been considered but are not persuasive for reasons made of record above.

New Objections Based on Amendment

Claim 70 is objected to a improperly referencing a Table. Referencing figures or tables in a claim is only proper when the information contained therein cannot be represented in any other manner (see MPEP 2173.05(s)). Further, the sequence rules require sequences to be claimed by their appropriate sequence identifier number and not Table number.

Status of Claims

Claims 14 and 16 are withdrawn in view of non-elected diseases. Claims 12, 13, 15, 31, 32 and 70-89 stand rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645